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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,367	06/03/2002	Henning Boettcher	MERCK 2370	8082

23599 7590 05/20/2003

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EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	**PAPER NUMBER**
1624	7

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/031,367	BOETTCHER et al.
Examiner	**Art Unit**
Emily Bernhardt	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-8 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicants are advised that the claims being examined are amended pages presented with the transmittal letter to the PCT US division. PTO staff cannot procedurally replace pages with original claim pages without following Rules governing amendments.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Acyl is of unknown scope except for the specific moieties recited on p.7 of the specification . However, the definition is made open-ended by the term "preferably" as to what other carbon ranges may be intended as well as other "substituted" derivatives.

2. "Such as", "for example" in the claims (1,2,8) makes it unclear what is actually being claimed- subject matter before or after the terms. See MPEP 2173.05 (d).

3. Second proviso in claim 1 is extraneous since R5 is only limited to H.

4. Claims 3,4,5 and 8 directed to compounds do not further limit the scope of main compound claim 1. Reciting intended uses in claims 4,5,7,8 has no material weight and is directed to non-statutory subject matter. Claim 3 simply recites provisos

already present in main claim 1 and thus does not serve to further narrow as a dependent claim should.

5. In claim 2 route c) other than the particular conversion recited it is not known what else is being claimed since no other reactants are set forth or products made therefrom and thus such language does not clearly set forth applicant's invention. Also in this claim it is not seen where in any of the recited step(s), solvates are being produced.

6. Is claim 6 intended as a composition or another compound claim? If a composition intended, carrier(s) should be present. Also what constitutes "assistants" vs "excipients" ? "Other active ingredients" is not set forth in the specification much less for an intended use as a co-ingredient.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4,5, 7 and 8 are rejected under 35 U.S.C. 101 because the claims are drafted in terms of "use" for the preparation of a medicament which has been held to be nonstatutory. Note Clinical Products v. Brenner 149 USPQ 475.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. Claims which embrace any solvate are nonenabled since generally not all solvents can form solvates with all compounds. There is no process enabling such a scope in the specification .

2. Specification is not adequately enabled for the scope of piperazines claimed which can have a variety of both mono- and bicyclo heterocyclics having up to 3 hetero atoms in Het^1 rings claimed. No such compounds are reported to have been made much less tested . There is thus no reasonable assurance as to what type of rings will work as there is no such basis in the prior art. Note Baldwin applied below for one particular hetero ring system teaches a different pharamceutical use. Receptor binding is known to be structure-sensitive in general. Note In re Surrey

151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a),August 2000 edition. Thus given the breadth of the claims, the level of unpredictability in the art and the lack of direction (i.e. working examples) provided as to what rings,ring systems as Het[1] might work, this rejection is being applied.

3. Should applicants amend nonstatutory claims to method claims, scope of uses recited in these claims is not remotely enabled. The notion that diseases such as Alzheimer's, all other neurological disorders, memory disorders, ALS,etc., etc. can be effectively treated by simply acting as 5-HT2a antagonists has not been substantiated by the current state of the art. Robichaud a very recent article on serotonin receptors does not acknowledge such uses can be treated but at best depression. Note disappointing results reported for psychoses in one compound having gone phase III clinical trials. Additionally, there is no dosage regimen for such a range of uses for instant compounds much less combined with other unknown "active ingredients" .

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldwin (US'604). Baldwin describes a compound within the instant scope for use as an antiarrhythmic agent. See eg.17 which is made by route a) claimed herein.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin (US'598). The compounds of Baldwin are taught for use as antiarrhythmic agetnts. While example 24 is excluded by applicants' proviso Baldwin teaches that the indole ring can be substituted with groups such as alkyl, halo, alkoxy as set forth in col.3 definition for R2 and R3 and can be made by one or more routes as claimed herein. Thus it would have been obvious to one skilled in the art at the time

the invention was made to modify eg.24 by placing other groups in place of hydrogen on the indole ring system and in so doing obtain various instant compounds for use taught by Baldwin and their preparation an obvious expedient in view of the teachings outlined above.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 031566. Although the conflicting claims are not identical, they are not patentably distinct from each other because they embrace overlapping subject matter- i.e. instant R4 as acyl covers benzoyl being claimed in the copending case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned 10/031566, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions

were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

The two references present in the file cited by the EPO has been noted. No IDS statement is seen for initialing. Has one been filed?

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier

numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600